UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 15-2666 (JNE/FLN)
This Document Relates to All Actions	**PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE DEFENDANTS' EXPERT TIMOTHY ULATOWSKI**

Plaintiffs bring this Motion to exclude the testimony of Defendants' regulatory expert, Timothy Ulatowski. Mr. Ulatowski is a former high-level employee of the U.S. Food & Drug Administration (FDA), where he served as a Director of Compliance as well as a Director in the Center for Devices and Radiological Health.[1] According to Mr. Ulatowski, "all [his] opinions are regulatory focused."[2] His opinions concern the clearance of the Bair Hugger devices under FDA §510(k).

Class II medical devices such as the Bair Hugger are not subjected to the FDA's stringent premarket approval (PMA) process. Rather, these devices are granted clearance under the far less demanding requirements of 510(k), which Mr. Ulatowski acknowledged is "a determination by the FDA that a product being offered in the application is substantially equivalent to a previously-legally-marketed product."[3] Mr. Ultatowski is being offered to testify that the design and labeling for the Bair Hugger "met regulatory requirements" under 510(k).[4] Mr. Ulatowski

[1] Exhibit 1, Deposition of Timothy Ulatowski, 12:1-12:2.
[2] *Id.* at 30:4.
[3] *Id.* at 53:16-19.
[4] Exhibit 2, Ulatowski Report, p 48, 66.

plans to tell the jury that the "FDA review of 510(k) marketing applications is rigorous."[5] Mr. Ulatowski also opines that the FDA clearance of the Bair Hugger devices under 510(k) provided "a reasonable assurance that the Bair Huggers were safe and effective."[6]

However, scores of federal courts have recognized Supreme Court precedent holding that the 510(k) process is not relevant to a jury's determination of a tort claim based on a product defect. These courts also recognize that even if the 510(k) process had any probative value, it would be far outweighed by prejudice and the potential for jury confusion. Indeed, Mr. Ulatowski's attempt to offer such opinions have been repeatedly barred in multiple individual cases and multidistrict litigation proceedings for exactly these reasons. Additionally, in this particular case, Mr. Ulatowski's are unreliable and contradicted by material evidence which he was not provided.

LEGAL STANDARD

Plaintiffs seek exclusion of Mr. Ulatowski's regulatory opinions because they are irrelevant and unreliable. "In order to be admissible, expert testimony must be both relevant to a material issue and reliable." *Margolies v. McCleary*, Inc., 447 F.3d 1115, 1120 (8th Cir. 2006). Under Fed. R. Evid. 401, evidence must be relevant and consequential, and under Fed. R. Evid. 702, opinions must be "based upon sufficient facts or data," and the expert must have "applied the principles and methods reliably to the facts of the case."

Plaintiffs also seek exclusion of Mr. Ulatowski's regulatory opinions because the prejudicial effect of his testimony far outweighs its probative value, if any. Under Fed. R. Evid. 403, the Court should exclude expert testimony when its probative value is negligible compared

[5] *Id*.
[6] Exhibit 2, Ulatowski Report, p. 35.

to a substantial danger of "unfair prejudice, confusing the issues, misleading the jury, undue delay, [or] wasting time."

ARGUMENT

I. Clearances Under FDA §510(k) are Irrelevant and Prejudicial in Products Liability Lawsuits.

"The 510(k) process is not a safety statute or administrative regulation." *Lewis v. Johnson & Johnson*, 991 F.Supp.2d 748, 755 (S.D.W. Va. 2014). "Since the §510(k) process is focused on *equivalence*, not safety, substantial equivalence determinations provide little protection to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 471 (1996) (emphasis in original); *see also Riegel v. Medtronic, Inc*., 552 U.S. 312, 323 (2008) ("§510(k) is 'focused on *equivalence*, not safety.'"). "The attraction of substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." *Medtronic, Inc*., 518 U.S. at 479, *quoting* Adler, 43 Food Drug Cosm. L.J. at 516. "The FDA thus prohibits manufacturers of devices cleared through the 510(k) process from making any representations that their devices have been approved by the FDA." *Lewis*, 991 F.Supp.2d at 755. For this reason, the 510(k) process is not relevant to a determination of the safety or effectiveness of a device in a tort action. *See, e.g., Cisson v. C.R. Bard, Inc*., 2013 WL 3821280, at *7 (S.D.W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own."); *see Bellew v. Ethicon, Inc*., 2014 WL 6674424, at *8 (S.D.W. Va. 2014) ("Bound by Supreme Court precedent, I cannot conclude that 510(k) clearance speaks to the safety or effectiveness of the [device].")

The most thorough recent examination of this issue in the context of multidistrict device litigation came last year, when the Fourth Circuit spoke directly to the irrelevant and prejudicial nature of 510(k) in affirming the exclusion of identical expert testimony:

> [Defendant's] evidence would have initiated a battle of experts: [Defendant] was prepared to characterize the review process as "thorough" and "robust" and the FDA's clearance of the Avaulta Plus as "an affirmative safety ... decision" based on "specific safety and efficacy findings." [Plaintiff] was prepared to argue, as she has done before this Court, that these characterizations wildly inflate the significance of the process, and that in any event [Defendant] failed to make necessary disclosures to the FDA.
>
> All of this, the district court reasoned, presented "the very substantial dangers of misleading the jury and confusing the issues." The court expressed concern that subjecting the jury to many hours, and possibly days, of complex testimony about regulatory compliance could lead jurors to erroneously conclude that regulatory compliance proved product safety. In other words, having a "mini-trial" could easily inflate the perceived importance of compliance and distract the jury from the central question before it -- whether [defendant's] design was unreasonable based on any dangers it posed versus the costs required to avoid them. While 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much that is specific. The vast majority of courts have said so, and having been thoroughly briefed not only by the parties but by several amici, we say so again today.

In re C.R. Bard, Inc., MDL. No. 2187, *Pelvic Repair System Products Liability Litigation*, 810 F.3d 913, 921–22 (4th Cir. 2016).

II. Mr. Ulatowski was Excluded in Prior MDLs on the Same Grounds

Consistent with the authority above, Mr. Ulatowski has been excluded from prior MDLs when he attempted to provide similar testimony regarding the FDA, 510(k), and regulatory compliance. In the *Nexgen* MDL, Mr. Ulatowski's report provided "a narrative description of the FDA's processes for regulation of medical devices, its 510(k) process in general, an overview of artificial knee devices, and the history of Zimmer's 510(k) submissions." *In re Zimmer NexGen*

Knee Implant Products Liability Litigation, 2015 WL 5145546, at *10 (N.D. Ill. 2015). Mr. Ulatowski has testified to these same matters in this case:

> Q. I notice your report provides a narrative description of the FDA processes for regulating medical devices; is that correct?
>
> A. Correct.
>
> Q. It has an overview of forced-air warming devices generally?
>
> A. Generally, yes.
>
> Q. It discusses a history of Arizant's 510(k) submissions?
>
> A. Right, to the degree that I could discover that on FDA's website.[7]

Additionally, Mr. Ulatowski likewise attempted to testify in *NexGen* that the defendant "substantially complied with FDA post-market regulatory requirements, as evidenced by the compliant content of their post-market procedures and implementation of those procedures." *Id.* at *16. The *Nexgen* court excluded all of his testimony regarding the 510(k) process, the defendant's compliance, or the adequacy of the product's warning. The court held that the 510(k) process was not relevant to "a device's safety and effectiveness." *Id.* at *14. The defendant in *Nexgen* argued, as 3M will likely argue here, that Mr. Ulatowski will not testify that 510(k) is a legal determination of safety or effectiveness:

> Rejecting this characterization of Ulatowski's opinions, Zimmer maintains that it "does not claim or offer Mr. Ulatowski to testify that the 510(k) process represents a final legal determination of safety and effectiveness that preempts or otherwise legally forecloses Plaintiffs' claims here." Given this concession, it is unclear to the court why the jury should hear Ulatowski "explain the process by which FDA reviewed the NexGen devices and the context in which these products were developed," as Zimmer suggests.

[7] *Id.* at 54:16 to 55:1.

Id. at *11. Moreover, the court in *NexGen* explained why Rule 403 required exclusion even assuming the testimony had some probative value:

> [A]ssuming any expert testimony on the 510(k) clearance process would have probative value at Ms. Batty's trial (a matter not free from doubt), it is "substantially outweighed" by the danger of misleading the jury. *See* Fed. R. Evid. 403. As the brief review of the differences between PMA review and 510(k) review outlined above suggests, there is significant risk that jurors may be led to believe that the 510(k) clearance that Zimmer's NexGen Flex system components received is equivalent to a finding of non-negligent design, which is an incorrect statement of law.

Id. at *14. The NexGen MDL court concluded by stating that "the FDA's finding of substantial equivalence, as a matter of law, is not a safety determination, and simply has too little probative value on the issue of whether the NexGen Flex system was defective, and whether those defects injured [plaintiff]." *Id.* at *15.

Similarly, the court in the *Ethicon* MDL likewise ruled that Mr. Ulatowski could not testify about 510(k) or regulatory issues, recognizing "the risks of leading the jury into the confusing domain of the FDA." *Bellew v. Ethicon, Inc.*, 2014 WL 6680356, at *10 (S.D.W. Va. 2014). The Ethicon MDL court held that "to the extent that Mr. Ulatowski's opinions implicate the 510(k) clearance process in general or with respect to the Prolift specifically, his opinion is improper and therefore EXCLUDED." *Id.* The court emphasized that it would "not tolerate the presentation of evidence that touches on or in any way alludes to the 510(k) clearance process." *Id.*

III. Mr. Ulatowski's Opinions are Unreliable.

Moreover, even if this Court were to decide that the 510(k) process had some relevance to the case, Mr. Ulatowski's opinion should still be excluded as unreliable. Most vitally, Mr. Ulatowski was not provided the 510(k) decision-making documentation relating to the Bair

Hugger 500 series, the first Bair Hugger model intended for operating room use, and these decision-making documents directly conflict with Mr. Ulatowski's testimony.

Regarding the clearance decision for the Bair Hugger 500 series, Mr. Ulatowski was asked what the FDA did to ensure safety:

> Q. What did the FDA do to determine that the Bair Hugger's expansion of use into the OR did not pose any new questions of safety?
>
> A. Well we don't have available to us the reviews by FDA, so we don't -- we cannot benefit from that.[8]

Mr. Ulatowski repeatedly referred to his inability to review the decision-making documents, stating "[w]ell I can't discuss the reviews without having them, and having them would shed more light on FDA's foundation for their finding of substantial equivalence…"[9] Lacking the actual documentation, Mr. Ulatowski attempted to explain the decision-making steps in the clearance of the Bair Hugger 500 for operating room use:

> Q. The first thing you have to determine is "Is the product a device?"
>
> A. Yes, generally, in a very general manner.
>
> Q. Now devices can be subject to different FDA regulations?
>
> A. Correct.
>
> Q. One of those regulations is 510(k)?
>
> A. Correct.
>
> Q. So then one of the next things you have to determine, is the device subject to 510(k)?
>
> A. Yes. You may. That may be a front-end decision or will have to remain as a back-end determination.

[8] *Id.* at 87:23 to 88:3
[9] *Id.* at 88:23-89:1; *see also* 93:2 to 93:5.

Q. And then one of the next…steps might be does the product have the same indication statement?

A. Right.

Q. And in this case you would conclude, no, it doesn't, and then that would trigger you to ask the question does that new indication for use present any safety questions?

A. Yes.

Q. That would be the proper way for a 510(k) reviewer to go about looking at this product?

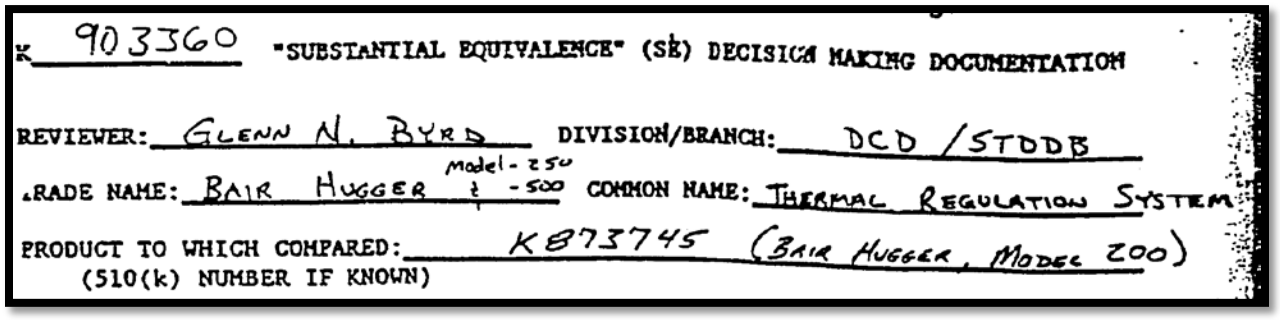
A. Yes.[10]

In other words, Mr. Ulatowski testified that the FDA reviewers would have determined the change in indications for OR use did not affect safety:

Q. From what I'm understanding from you, the FDA understood that there was a change in indications for use but concluded that those changes did not affect health and safety questions.

A. I think that's the case.[11]

Unbeknownst to Mr. Ulatowski, 3M was in possession of the 510(k) decision-making documents for the clearance of the Bair Hugger 500 series and produced them to the Plaintiffs.[12] However, they were not given to Mr. Ulatowski.


K 903360 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

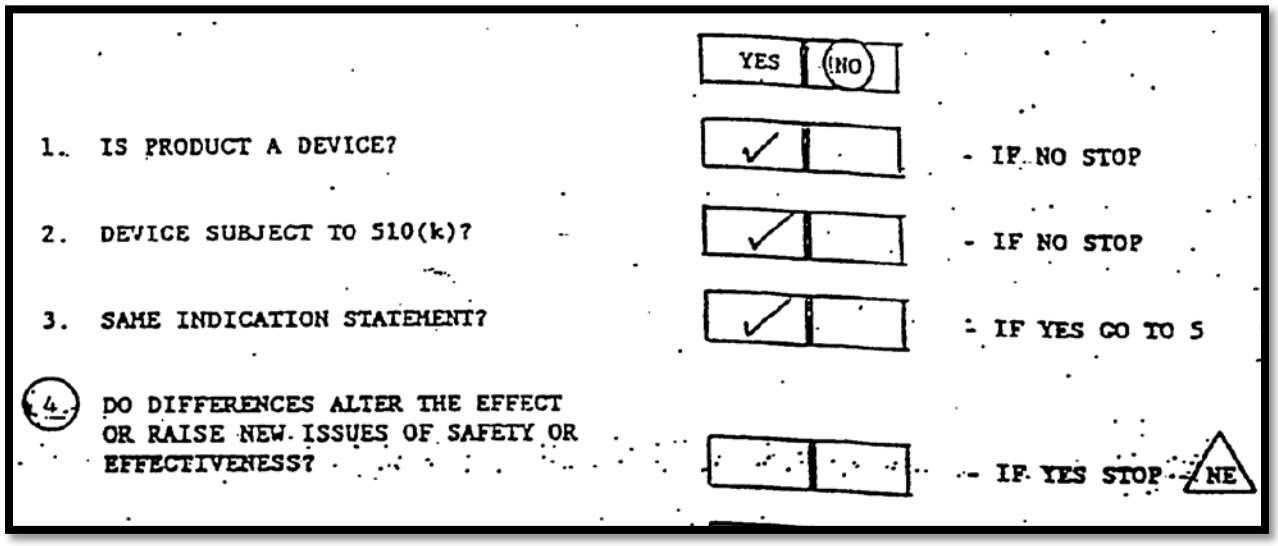
REVIEWER: GLENN N. BYRD DIVISION/BRANCH: DCD / STODB

TRADE NAME: BAIR HUGGER model - 250 & - 500 COMMON NAME: THERMAL REGULATION SYSTEM

PRODUCT TO WHICH COMPARED: K873745 (BAIR HUGGER, MODEL 200)
(510(k) NUMBER IF KNOWN)

[10] *Id.* at 156:12 to 157:16.
[11] *Id.* at 164:15 to 164:22.
[12] Exhibit 3, 510(k) Decision-Making Documentation, 3MBH00047439 – 42.

As these decision-making documents show, the FDA reviewer believed, erroneously, that the Bair Hugger 500 series had the same indication statement as the predicate device. By erroneously finding no change in the indication statement, the reviewer was not required to complete step No. 4 on the evaluation flowchart, concerning the potential safety effect of any change.

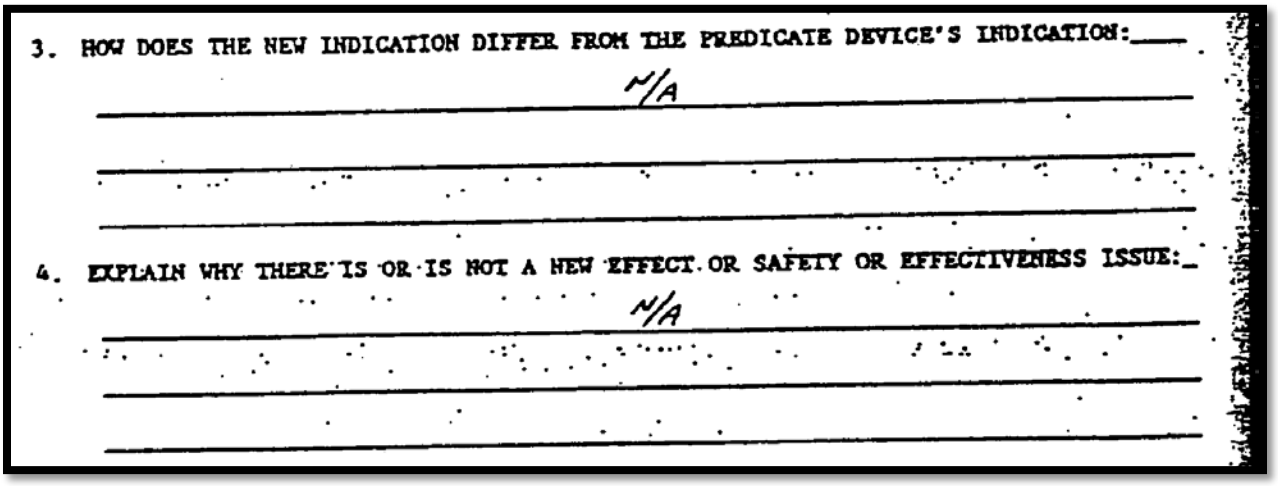


Due to the erroneous finding, the reviewer was not required to make any assessment of whether a change in indications for use (IFU) had any impact on safety or effectiveness, as Mr. Ulatowski acknowledged:

> Q. If the IFUs are not changed…you don't have to ask if there's any changes in safety and effectiveness for the IFUs because those IFUs haven't changed.
>
> A. Correct.[13]

As shown in the decision-making documentation, the reviewer therefore did not make any determination about a potential new impact on safety or effectiveness:

[13] Ulatowski Dep. at143:20 to 143:24


3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:
N/A
4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:
N/A

After reviewing the decision-making documentation during his deposition, Mr. Ulatowski confirmed that the omission occurred in this case due to a finding that indications for use had not changed:

> Q. And you see where it says "DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?" Do you see where it says that?
>
> A. Yes.
>
> Q. That question was not answered; correct?
>
> A. Right. It wouldn't have to be answered.
>
> Q. Right. Because you can skip it if you find it has the same indications statement.
>
> A. Correct.[14]

Further undermining Mr. Ulatowski's opinions was his inability to support the opinion that the 510(k) clearance was based on valid scientific evidence of safety:

> Q. What we are talking about is what you came to in your report, which is a statement that there is valid scientific evidence of the Bair Hugger's use in operating rooms and

[14] Exhibit 1, Ulatowski Deposition, 169:17-25

> that that evidence existed at the time of the Bair Hugger's clearance, and what I think I'm understanding from you is that when I am here today to ask you what evidence that is, what evidence you're relying on to make that opinion, you are telling me today in deposition you will not be able to give me that answer.
>
> A. I'm not prepared to give you that answer today.[15]

The reliability issues extend to other aspects of Mr. Ulatowski's opinions regarding compliance with regulatory guidelines. For example, Mr. Ulatowski gave opinions on warnings that contradict the very FDA guidelines he cited. Mr. Ulatowski testified that there was no need to include warnings with the device, stating that a warning was not necessary under FDA guidelines because of "the lack of a direct causal relationship of infections to forced-air warming.[16] However, the FDA Bluebook Guidance documents cited by Mr. Ulatowski state that "a causal relationship need not have been proved."[17] Rather, the guidance documents state that a warning is appropriate "if there is reasonable evidence of an association of a serious hazard with the use of the device."[18]

Moreover, Mr. Ulatowski's opinions regarding the purpose and effectiveness of 510(k) clearances is contradicted by the FDA's own findings. Mr. Ulatowski agreed that an internal audit ordered by the FDA Commissioner in 2011 found "that the 510(k) process was not designed to determine whether a new device provides a reasonable assurance of safety."[19] Nonetheless, Mr. Ulatowski stated the opposite is true in his report, opining that "there is reasonable assurance that a Class II device is safe and effective when it meets all the general controls and any special controls," and that the FDA clearance of the Bair Hugger provided "a

[15] *Id.* at 134:8 to 134:20
[16] *Id.* at 247:24 to 248:1
[17] *Id.* at 252:10 to 252:11
[18] *Id.* at 241:9 to 241:11
[19] *Id.* at 65:17-19.

reasonable assurance that the Bair Huggers were safe and effective."[20] The FDA committee also found "that congressional appropriations for the operation of 510(k) clearance have been unstable and frequently inadequate throughout its lifespan."[21] Mr. Ulatowski acknowledged that the committee found worrying deficiencies in the 510(k) program, including the finding that "the Center for Devices and Radiological Health does not have an adequate mechanism to regularly assess the quality, the consistency, and the effectiveness of the 510(k) program."[22] Ultimately, Mr. Ulatowski admitted that "it's the manufacturer, not the FDA, who is primarily responsible for the assurance of safety of medical devices."[23]

An opinion is not admissible unless it "rests on a reliable foundation." *Allen v. Brown Clinic, P.L.L.P.*, 531 F.3d 568, 573 (8th Cir. 2008). Expert opinions must be "based upon sufficient facts or data," and the expert must have "applied the principles and methods reliably to the facts of the case." *See* Fed. R. Evid. 702. Mr. Ulatowski did neither. He failed to review the necessary evidence to give opinions about the safety determinations in the 510(k) process, and that evidence contradicts his opinion. Moreover, his opinions conflict with the FDA materials he did review. Therefore, not only is Mr. Ulatowski's testimony irrelevant and prejudicial, but it is also unreliable.

IV. Mr. Ulatowski's Personal Involvement in the Bair Hugger's Regulatory History Raises Doubts Regarding Bias and Invites Prejudice.

Further weighing in favor of exclusion is Mr. Ulatowski's numerous occasions of prior personal involvement with Bair Hugger regulatory matters, much of which he initially denied in deposition. Mr. Ulatowski's personal connection to Bair Hugger clearance and enforcement

[20] Exhibit 2, Ulatowski Report, p. 35.
[21] Exhibit 1, Ulatowski Deposition, 66:9-13.
[22] *Id.* at 72:5 to 72:8.
[23] *Id.* at 76:22 to 77:1.

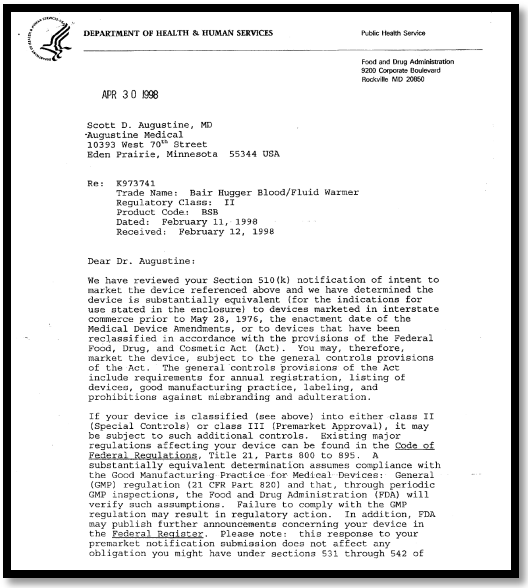
issues presents the appearance of a conflict of interest, as well as an extreme risk of prejudice and jury confusion.

During his deposition, Mr. Ulatowski was asked about the possibility of an appearance of conflict of interest if someone personally involved with the clearance of a Bair Hugger product later testified about the adequacy of the clearance for that product line. Mr. Ulatowski dismissed the possibility of such a conflict, stating that he was never involved in any kind of clearance for the Bair Hugger:

> Q. But in this case we don't have the kind of conflict we were just talking about because you were never involved in any kind of 510(k) approval for this product; right?
>
> A. Clearance for the product, no.[24]

However, Defendants' production of documents revealed at least once instance of Mr. Ulatowski personally approving a Bair Hugger 510(k) application, when he signed off on the clearance for the addition of the Bair Hugger Blood/Fluid Warmer accessory to the Bair Hugger system.[25]

[24] *Id.* at 43:25 to 44:4
[25] Exhibit 4, 510(k) Approval Letter, 3MBH01696526-27.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1998

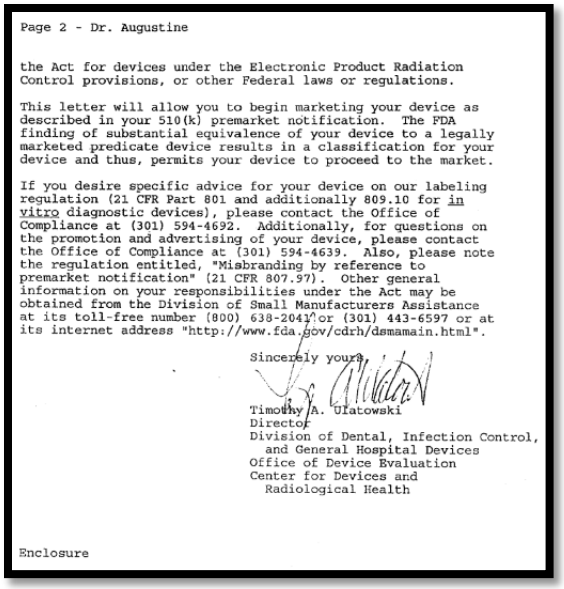
Scott D. Augustine, MD
Augustine Medical
10393 West 70th Street
Eden Prairie, Minnesota 55344 USA

Re: K973741
Trade Name: Bair Hugger Blood/Fluid Warmer
Regulatory Class: II
Product Code: BSB
Dated: February 11, 1998
Received: February 12, 1998

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of



Page 2 - Dr. Augustine

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Mr. Ulatowski claims that no conflict could exist because the Bair Hugger accessory that was the focus of the application was not used in the Plaintiffs' surgeries. However, when Mr. Ulatowski approved the addition of the accessory to the Bair Hugger system, it would have been necessary to examine and evaluate the system as a whole. Mr. Ulatowski's approval of a clearance involving the Bair Hugger system could be seen as an endorsement of the product such that it might make him less likely to state that the product is anything but safe in this litigation. Moreover, Mr. Ulatowski's hairsplitting may not be understood by a jury. There is substantial risk that the jury will see Mr. Ulatowski as a witness for the FDA, supporting the FDA clearance decisions and the safety of the product.

This problem is compounded by the fact that Mr. Ulatowski was sent a letter in 2010 from the Defendants directly addressing the issues which are disputed in this lawsuit.[26] Despite the presence of this letter in Defendants' production, it had not been provided to Mr. Ulatowski prior to his deposition, and therefore he initially denied ever reviewing these matters:

[26] Exhibit 5, Letter from Arizant to FDA, 3MBH00970030-31.

> Q. When it comes to the allegations of airborne contamination, did you have any personal involvement at all at the FDA to reviewing those allegations?
>
> A. No.[27]

However, the 2010 letter, sent to the Director of Postmarket Surveillance and to Mr. Ulatowski as the Director of Compliance, discusses the MedWatch report submitted by Dr. Scott Augustine, and encloses a copy of the report for review while downplaying its significance. Mr. Ulatowski testified after reviewing the letter that he "has no knowledge of it" and that it was "unlikely" he read it.[28] Nonetheless, this letter presents another appearance of a potential conflict as well as a likely source of unfair prejudice.

In addition, Mr. Ulatowski was also the author of a warning letter sent to Defendants due to violations of adverse event reporting procedures involving burn injuries:

> Q. One of the people that you made an advisory action to is your current client.
>
> A. Correct.
>
> Q. And that advisory letter concerned adverse events.
>
> A. Correct.
>
> Q. Those adverse events, those were burns; right?
>
> A. That was associated, yes. Right.
>
> Q. And there were burns that had not been properly reported by the company.
>
> A. There were reporting issues that were observed.[29]

The fact that Mr. Ulatowski was involved in compliance efforts regarding the Bair Hugger product is a further source of prejudice and potential confusion. Mr. Ulatowski's

[27] Exhibit 1, Ulatowski Deposition, 224:11-14.
[28] *Id.* at 231:14-20.
[29] *Id.* at 51:13-52:1.

involvement in these events followed by his presence in the courtroom could be interpreted by a juror as an endorsement of safety by the FDA. Ultimately, Mr. Ulatowski's personal connection to events in the Bair Hugger's regulatory history may cause jurors to erroneously equate Mr. Ulatowski's testimony with that of the FDA, in spite of whatever limiting instructions are given to the contrary. In light of the numerous other problems discussed above, the potential prejudice from Mr. Ulatowski's personal connection to the facts of the case weighs further in favor of the exercise of the court's gatekeeping function.

V. Mr. Ulatowski Lacks Expertise and Foundation to Address to any Non-Regulatory Issues.

In addition to excluding his testimony on regulatory issues, this Court should also exclude any potential testimony regarding topics in which Mr. Ulatowski admits to a lack of expertise. As Mr. Ulatowski concedes, he does not "have any medical opinions in [his] report."[30] He does not hold himself out an expert "in any kind of surgical areas such as orthopedic surgery."[31] Mr. Ulatowski has no expertise in biomedical engineering, filtration, HVAC, operating room design, particulate flow, statistical analysis, infectious disease, or epidemiology.[32] Mr. Ulatowski testified that his report does not contain these kind of opinions, yet in terms of his trial testimony he intends to offer in his matter, he cryptically answered: "But who knows?"[33] Mr. Ulatowski acknowledged that his report is limited to the regulatory scheme:

> Q. So in other words, you may be giving us opinions about whether or not the defendant complied with the regulatory scheme that you oversaw during your many years at the FDA, but at the same time you will not be giving an opinion, a medical opinion, about the benefits of a Bair Hugger in orthopedic surgery. Is that fair?

[30] *Id.* at 28:15-16
[31] *Id.* at 31:2-5
[32] *Id.* at 34:12-14; 271:1-23; 364:4-10.
[33] *Id.* at 271:25

A. Generally, no…I will not.[34]

Regarding "the degree of medical risk from the use of the Bair Hugger in orthopedic surgeries," Mr. Ulatowski said he "would defer to other defendants experts in regard to that."[35] Mr. Ulatowski also testified that he will not be giving an opinion whether "the Bair Hugger is or is not defective,"[36] nor will he testify that "there is a reasonable assurance from a medical point of view that the device is safe."[37] Given that Mr. Ulatowski is only qualified to testify regarding regulatory compliance – an irrelevant and prejudicial topic – he should be excluded as an expert in this matter.

CONCLUSION

Plaintiffs respectfully move this Court for an order excluding Mr. Ulatowski from testifying in this matter. His regulatory opinions are irrelevant, prejudicial, and unreliable. Moreover, his personal connection to the Bair Hugger's regulatory history invites further prejudice. Finally, Mr. Ulatowski does not possess any relevant qualifications beyond his regulatory background, and therefore should not be permitted to testify regarding other any other undisclosed issues.

Respectfully submitted,

Dated: September 12, 2017

[34] *Id.* at 32:15 to 33:3.
[35] *Id.* at 34:3-11
[36] *Id.* at 58:25 to 59:3.
[37] *Id.* at 190:1-6.

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